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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,750	10/25/2001	Jenny Louie-Helm	3100-0003	1055

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REED INTELLECTUAL PROPERTY LAW GROUP
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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,750	LOUIE-HELM ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,39,40 and 45-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37,39,40 and 45-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SD

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination filed under 37 CFR 1.114, amendment, remarks and declarations, all filed 07/15/05. Claims 1-37, 39, 40, 45-54 and new claims 55 and 56 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 07/15/05 has been entered.

Claim Objections

2. Claim 55 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-9, 12-16, 18-23, 26-34, 36-40 and 45-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell et al. (US 5,972,389).

Shell discloses a controlled release oral dosage form that comprises drug particles dispersed in swellable/erodible polymer where the erodible polymer is polyethylene oxide; the

dosage form is formulated as tablet or capsule and liposomes or nanoparticles or enteric-coated drug particles are examples of drug containing vesicles that can deliver drugs to the site of interest (abstract, column 1, line 48 to column 2 line 36, column 3, lines 26-44, column 4, lines 5-18, column 7, lines 60-62, column 8, lines 4-55). Ciprofloxacin (column 5, line 10), bismuth subsalicylate, bismuth citrate, antibiotics such as amoxicillin, tetracycline, chlarithromycin, thiamphenicol, metronidazole which are Helicobacter pylori eradicating drugs (column 5, lines 46-49 and claims 6-9), gastric lowering agents such as omeprazole, ranitidine, cimetidine, famotidine (column 5, lines 49-55) are examples of drugs delivered by the dosage form of Shell. Shell also teaches that nifedipine, acyclovir, alprazolam, phenytoin, carbamazepine, clozapine, lovastatin and nitrofurantoin are other drugs that can be delivered by the vesicle (claim 5).

The molecular weight of the polyethylene glycol in Shell ranges from 1×10^5 to 7×10^6 kD (claims 3 and 4). The weight ratio of drug to polymer is 2:3 to 9:1 (column 8, lines 26-31).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. In claim 9, the presence of a mixture of polyethylene oxide-co-propylene oxide is optional so that Shell meets the limitation of claims 1. Shell teaches a range of drug to polymer and one of the points in the taught range in Shell anticipates a point in the recited range in claims 13-16. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Also the molecular weight of the active agent is a property of the active agent and because the instant claims have not recited any drugs that

would have the molecular weight recited in instant claim 21 and because some of the drugs recited in the claims are the same as those taught by Shell, Shell meets the limitations of claim 21. Therefore, the teachings of Shell meet the limitations of the claims.

5. Claims 1-7, 10, 12, 17-23 and 45-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Shell (US 5,007,790).

Shell discloses a sustained release oral dosage form in tablet or pill and the dosage form comprises drugs and cross-linked hydrophilic and water swellable polymer (abstract, column 2, line 29 to column 3 line 15 and claims 1-9). The drugs included in the dosage form of Shell are calcium carbonate, cimetidine, ranitidine, indomethacin, ibuprofen, naproxen, prednisone, prednisolone, dexamethasone, piroxicam, aspirin, nifedipine and potassium chloride potassium supplement (column 2, lines 28-35); carboxymethyl cellulose, alginate, polyvinyl alcohol and chitin (column 3, lines 7-16) are examples of cross-linked polymer.

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is recited, Shell meets the limitations of the claims. Claims 45-49 recite the properties and how to optimize the composition, which are not accorded patentable weight to the composition. Also the molecular weight of the active agent is a property of the active agent. Shell reads on the scope of the claims.

Applicants argue:

That Shell 1 (US 5,972,389) discloses plurality of pellets or particles as tablets while the tablet of the instant claims as amended is not made up of plurality of pellets or particles. Same argument was presented for Shell 2 (US 5,007,790).

Applicants' argument is not persuasive because the Shell references disclose tablet formulation ands specifically discloses tablets formed by compression. The claims do not exclude particles.

6. Claims 1-7, 10, 17-22 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Uemura et al. (US 4,695,467).

Uemura discloses sustained release tablet; the tablet comprising disintegrable granules that contain a drug, disintegrating agents selected from starch derivatives, gums, cellulose derivatives and ion exchange resins, and water soluble polymer selected from cellulose derivatives, synthetic water soluble polymers and polysaccharide and excipient (abstract, column 3, lines 10-21). The water-soluble cellulose derivatives are hydroxypropylmethylcellulose, methylcellulose, hydroxypropylcellulose and carboxymethylcellulose; synthetic water-soluble polymers are polyvinylpyrrolidone, cross-linked polyvinylpyrrolidone and polyethylene oxide; and pullulan and dextran are examples of polysaccharides (column 3, lines 33-41).

Claims 2-5 are directed to the property of the dosage and since a property of a composition is not separable from the composition, and in this case the dosage form, Shell meets scope of the limitations of the claims. Claim 1 is a dosage form that comprises a pharmacologically active agent and hydrophilic polymer. The solubility of the active agent at the designated temperature is a property of the active agent and since no specific active agent is

recited and the molecular weight of the active agent is a property of the active agent. The teaching of Uemura meets the limitations of the claims.

Applicants argue:

That Uemura does not disclose solid dosage form because the Uemura discloses plurality of discrete granules encapsulated to form a unit dose, which does not swell in such a manner as to promote gastric retention.

Applicants' argument is not persuasive because granules are solid and Uemura discloses the polymers of the instant claims and therefore the swelling of the granules translates to the swelling of the dosage.

7. The rejection of claims 1, 6-8, 10, 11, 23, 24, 25, 30, 34 and 35 under 35 U.S.C. 102(e) as being anticipated by Vandecruys et al. (US 6,667,060) is withdrawn in light of applicants' declaration ante-dating the claimed invention so that Vandecruys cannot be prior art under 35 USC 102(e).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 6, 11, 23-25, 34 and 35 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Patel et al. (US 6,248,363).

Patel discloses a tablet formulation (column 36, line 3) comprising zein or xanthan gum (column 40, lines 63 and 64) and active agents such as paclitaxel, topiramate and metformin

(column 5, line 59; column 6, lines 3, 43 and 53; column 9, line 3). Patel anticipates the claims. In the alternate, if the listing of the various drugs do not represent specific disclosure of paclitaxel, topiramate and metformin in tablet formation in xanthan gum containing matrix, it would be obvious that a person of ordinary skill in the art would use any of the disclosed drug in tablet formulation having xanthan gum matrix at the time the invention was made, among the list of disclosed drugs are paclitaxel, topiramate and metformin. Xanthan gum is a biocompatible hydrophilic polymer. One having ordinary skill in the art would have been motivated to prepare the dosage form for oral delivery of paclitaxel, topiramate and metformin.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
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